

Notice of Allowability

Application No.

09/594,972

Examiner

Bao-Thuy L. Nguyen

Applicant(s)

GOERLACH-GRAW ET AL.

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Appeal Brief filed on 22 August 2005 and Examiner's Amendment.
2. ☒ The allowed claim(s) is/are 15-26 which have been renumbered from 1-12 respectively.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Bao-Thuy L. Nguyen
Primary Examiner
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10/27/05

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jill Woodburn on 25 October 2005.

The application has been amended as follows:

In the claims:

Claim 15 (currently amendment) An element for the determination of an analyte in a liquid, the element comprising:

a sample application zone,

a detection zone located downstream from the sample application zone and being the last zone of the element that allows liquid transport, the detection zone being devoid of a binding reagent that would enable detection of the analyte;

a zone containing immobilized analyte or analyte analogue located between the sample application zone and the detection zone,

~~[a material that enables liquid transport between the zones,]~~

a conjugate impregnated in a matrix material located upstream of the zone containing immobilized analyte or analyte analogue, the conjugate can be detached from the matrix material by liquid and comprises a first bioaffine binding partner

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capable of a specific binding reaction with the analyte to be determined and a first detectable label, wherein the first detectable label is a low molecular organic molecule, and

a universal conjugate, located upstream of the zone containing immobilized analyte or analyte analogue, which can be detached by liquid and comprises a second bioaffine binding partner and a visually detectable label, the second bioaffine binding partner is capable of a specific binding reaction with the first detectable label, wherein the visually detectable label is a direct visually detectable label formed to carry out the determination of the analyte in the detection zone;

wherein the matrix and the zones are made from liquid permeable transport materials.

Abstract

2. The abstract of the disclosure is objected to because it is too long. See MPEP § 608.01(b). The following abstract has been entered:

The invention concerns an element for the determination of an analyte in a liquid by means of a specific binding reaction of two bioaffine binding partners containing in or on material which enables liquid transport between the zones. The element comprises a sample application zone; a detection zone located downstream thereof that is devoid of binding reagents and is the last zone on the element that allows liquid transport; a zone containing immobilized analyte or

analyte analogue between the sample application zone and the detection zone; and impregnated conjugate that can be detached by liquid located in the sample application zone or upstream or downstream thereof composed of a bioaffine binding partner capable of a specific binding reaction with the analyte to be determined and a detectable label.

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance:

The instant claims define over the prior art of record because the prior art of record fail to teach a detection zone that is the last zone on a support that enables liquid transports and that is devoid of any reagents that enable detection of analytes.

Complexes between analytes, labeled binding partner and a universal conjugate is accumulated in the detection zone by virtue of this zone being the last zone of the element that allows liquid transport.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571)

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272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
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